EXHIBIT A

REPORT FOR ZOLOFT MDL LITIGATION

Expert Report of Robert D. Gibbons, PhD.

March 27, 2015

Qualifications

1. I am a Professor of Public Health Sciences, Medicine, and Psychiatry, and the Director of the Center for Health Statistics at the University of Chicago. I am a Fellow of the American Statistical Association and a two-time recipient of the American Statistical Association's Youden Award for statistical contributions to the field of Chemistry (2001 and 2006), and the 2009 Outstanding Statistical Application Award for the development of new and innovative statistical approaches to drug safety, and for clarifying the relationship between antidepressant pharmacotherapy and suicide. I have received the Harvard Award for lifetime contributions to the fields of Psychiatric Epidemiology and Biostatistics. I have received the Rema Lapouse Award from the American Public Health Association for lifetime contributions to the fields of Psychiatric Epidemiology and Biostatistics and the Long-Term Excellence Award in Health Policy Statistics from the American Statistical Association. I am a Pritzker Scholar at the University of Chicago. I am the founding member of the Mental Health Statistics Section of the American Statistical Association. I am an elected member of the Institute of Medicine (IOM) of the National Academy of Sciences (NAS), and served for six years on the IOM Board on Health Sciences Policy.

2. I am the author of over 250 peer-reviewed scientific papers, and five books, a large number of which are in the interface between statistical theory and practice and mental health. Two of these books are considered foundational in the area of environmental statistics (*Statistical Methods for Groundwater Monitoring* (1st edition 1994, 2nd edition 2009) and *Statistical Methods for Detection and Quantification of Environmental Contamination* (2001) with David Coleman, both published by John Wiley & Sons). The 2001 book received the distinction of being in the top 5 books for statisticians from the American Statistical Association. My book with Don Hedeker, *Longitudinal Data Analysis*, also published by John Wiley & Sons and soon to be in its 2nd edition, presents a comprehensive overview of methods for the analysis of longitudinal data. I have just completed a new book entitled *Statistical Methods for Drug Safety*, to be published by Chapman & Hall in June of 2015.

3. I have served as a member of the Institute of Medicine Committee on the Prevention of Suicide, and developed the Statistical Details Appendix of that report that provides an overview of statistical methods for the analysis of suicide and attempts. I also served on the Institute of Medicine Committee on U.S. Drug Safety, which recommended major changes in the way in which the Food and Drug Administration ("FDA") evaluates safety and post-marketing surveillance of pharmaceuticals. These recommendations have been adopted by Congress and are now being implemented at FDA. I personally wrote the recommendation that led to the creation of the new FDA Sentinel Network that is using large-scale medical records and claims data to evaluate post-marketing drug surveillance and was a founding member of its Scientific Advisory board. I also served on the FDA Scientific Advisory Committee on Suicide and Antidepressants in Children. I am the primary author of the chapter on post-marketing drug surveillance in the 2010 *Annual Review of Public Health*.

4. I have extensive experience in the design and analysis of both Randomized Clinical Trials (RCTs) and observational studies. As an example, I analyzed all of the RCTs of Xanax for the Upjohn Company in support of their New Drug Application ("NDA"). I have recently re-analyzed all of the placebo controlled RCT data on safety and efficacy of Prozac, Effexor, and Chantix and published the results of these analyses in the leading psychiatric journals (*JAMA Psychiatry* and the *American Journal of Psychiatry*). I also direct the statistical core for one of a handful of Centers for Education and Research on Therapeutics (CERT) funded by the Agency for Healthcare Research and Quality. I have also been a member of a data safety monitoring board for a large-scale multicenter RCT. With respect to observational studies and pharmacoepidemiologic studies in particular, I have worked with several large databases to evaluate antidepressants and antiepileptic drugs and the risk of suicidality. The results of all of these observational studies were published in the leading psychiatric and drug safety journals. I have particular expertise working with large medical claims databases covering the lives of 100 million people in the study of the safety of pharmaceuticals.

5. I received my doctorate in statistics and psychometrics from the University of Chicago in 1981. I mentored numerous doctoral students at the University of Illinois

at Chicago where I was a Professor of Biostatistics from 1981-2010. In 2010, I joined the faculty of the University of Chicago, where I am a Professor of Biostatistics and direct the Center for Health Statistics. I teach the advanced Statistical Applications course that is offered in the departments of Statistics and Public Health Sciences. I continue to mentor several doctoral students in a variety of departments across the University of Chicago.

6. My CV, which includes my publications in the last 10 years, is attached as Appendix A to this expert report. In the last 4 years, I have testified as an expert in deposition or trial in the following cases:

   - Depositions: *In re Chantix (Varenicline) Products Liability Litigation*, MDL No. 2092 (N.D. Ala.) May 4, 2012 & September 12, 2012
   - Deposition: *In re Denture Cream Products Liability Litigation,* No. 09-2-51-MD-Altonaga (S.D. Florida) 8/16/2013
   - I am being compensated at an hourly rate of $850 for preparation and $1,000 for deposition and testimony.

Assignment and Materials Relied Upon

7. In this case, I have been given a very specific assignment; to review Professor Nicholas Jewell's methodology relating to his re-analysis of data taken from published studies, presented as a part of his Frye motion testimony and his MDL report. Specifically, I address the methodology for Dr. Jewell's re-analysis of the Huybrechts study supplementary data comparing depressed patients who filled one or more prescriptions of Zoloft in the 1st trimester versus patients who filled a prescription prior to the 1st trimester but had a supply of Zoloft that extended into the 1st trimester of pregnancy. I have also been asked to provide an overview of my opinion regarding the statistical basis for the existence of an association between Zoloft and cardiovascular birth defects and if there is an association, does the evidence support a causal link.

8. Appendix B contains a list of the materials I considered in reaching my conclusions.

Summary of the Literature

9. Overall, there is a large body of epidemiologic evidence showing that Zoloft is not associated with increased risk of birth defects, including cardiac birth defects.

10. Most studies that focused on cardiac birth defects were unable to control for confounding by indication (i.e., behaviors that are associated with depression which themselves put infants at increased risk for birth defects). As newer studies have become available, it is clear that there is significant confounding by indication and that when such confounding is properly considered, children of women taking SSRIs, including Zoloft, during pregnancy have virtually identical risk of cardiac birth defects as children of depressed mothers who either paused treatment during pregnancy or were depressed but did not take antidepressants during the first trimester of their pregnancy.

11. The absence of an association between Zoloft and cardiac birth defects necessarily means there is no causal link. But even if one were to assume that there was a demonstrated association, there is no evidence of causation. With respect to cardiovascular birth defects, including major cardiac malformations, considering the epidemiologic evidence as a whole, there is no causal association with use of Zoloft.

12. Depressed women have several risk factors for having children with cardiac birth defects including increased rate of smoking, older age, purchase of other psychiatric medications, obesity, missed obstetric appointments, poor diet and sleep, alcohol use, and use of illicit drugs, among other risk factors (Huybrechts, 2014). Well-controlled studies have demonstrated that depressed women have an increased background risk of birth defects compared to the general population independent of whether they are taking SSRIs.

13. Jimenez-Solem (2012) studied pregnancies in Denmark. Their key finding as it relates to this case was based on comparison between depressed women who took Zoloft during the 1st trimester of pregnancy (n=817) versus those that paused their antidepressant treatment 3 months prior to pregnancy, but restarted treatment with the same antidepressant after pregnancy (n=806), hence the term “paused.” Although Jimenez-Solem compared both Zoloft exposed and paused groups to the unexposed

group separately and found similar results, they did not report the results of a direct comparison of Zoloft exposed versus antidepressant paused subjects. Both Professor Jewell and I have performed this comparison, and for Zoloft we both find that there was not a significant association between treatment and cardiac birth defects overall (OR=1.61, 95% CI=0.76, 3.42) or for septal defects as a subgroup (OR=1.35, 95% CI=0.58, 3.17), or for ventricular (OR=0.98, 95% CI=0.36, 2.72) or atrial (OR=1.32, 95% CI=0.41, 3.43) septal defects in particular.

14. Huybrechts (2014) studied pregnancies in the United States. With respect to this case, they performed a comparison of women who were depressed and took Zoloft (n=11,056) to depressed women who did not take antidepressants during the 1st trimester of their pregnancy (n=180,564) while adjusting for additional confounders using propensity score stratification and high dimensional propensity score matching. Women were considered to be exposed if the days of antidepressant supply overlapped with the 1st trimester of pregnancy. They reported Zoloft-specific results for all cardiac defects, right ventricular outflow defects, and ventricular septal defects. No association was found for all cardiac defects (OR=1.09, 95% CI=0.88, 1.34), right ventricular outflow defects (OR=1.12, 95% CI=0.67, 1.88), or ventricular septal defects (OR=1.04, 95% CI=0.76, 1.41). This is the largest well controlled study to date that has disentangled the effects of the indication for treatment from the effects of treatment.

15. Ban (2014) compared rates of cardiac defects among 757 depressed women exposed to Zoloft during the 1st trimester of pregnancy to 23,833 depressed but unmedicated women and found no significant association between Zoloft and cardiac birth defects (OR=1.39, 95% CI=0.70, 2.74).

16. There is also no apparent dose-response relationship between Zoloft and cardiac birth defects as shown by Huybrechts (2014). In the depression-restricted propensity-score stratified cohort, no association was found for any dosage group (highest dosage or first dosage) and there was no evidence of increasing risk with increasing dosage: low dose OR=1.06 (0.79, 1.42), medium dose OR=1.25 (0.94, 1.68), high dose OR=0.98 (0.13, 7.23).

17. Review of the best newly available studies which have controlled for confounding by indication for treatment (i.e., depression) show no evidence of an association between exposure to Zoloft during the first trimester of pregnancy and cardiac birth defects in general and septal defects in particular.

Accepted Statistical Methodology

18. A priori definition of experimental design and statistical methods is a fundamental element of reliable epidemiological research. Using this method, an investigator formulates a hypothesis, designates control and exposure groups, and specifies statistical methodology in advance of the gathering of the data, then gathers data, and then applies the predetermined methods in analysis of those data. Deviation from this methodological sequence is referred to as "post-hoc" analysis or "data dredging." Division of data into new subgroups after the results are known introduces the potential for chance association. Post-hoc analysis can be useful for hypothesis generation, but not for hypothesis testing. For example, in a new drug application submitted to the FDA, the study as designed may have failed to reject the null hypothesis; however, a post-hoc subgroup analysis restricted to older patients or patients with a more severe form of the illness may show significant results. In such cases, FDA invariably requires that a new study be carried out in the subgroup of interest to confirm the results of the post-hoc analysis which may simply have been due to chance.

19. Professor Jewell's re-analysis of the Huybrechts (2014) study is such a post-hoc analysis. However, there is no apparent need for re-analysis of these data since the original study design and analytic approach are of high quality and were deemed appropriate by the authors and by peer reviewers. The only motivation I can discern for Professor Jewell's re-analysis of the data is the fact that the analyses presented in the published studies found no increased risk of cardiac defects associated with Zoloft and were therefore inconsistent with Professor Jewell's claim that Zoloft increases the risk of cardiac defects. Professor Jewell's re-analysis does not improve upon, but rather is of substantially lower quality than, the analyses provided in the peer-reviewed publications from which he extracted the data. The statistical difference he

presents is not reflective of the "true" relationship between Zoloft and cardiac malformations, but rather provides an illustration of the perils of post-hoc analysis as I will illustrate in the following sections.

Professor Jewell's Re-analysis of Huybrechts (2014)

20. Although the analysis for Zoloft reported by Huybrechts (2014), based on their definition of exposure, restricting the cohort to depressed mothers, and employing propensity score stratification to control for the effects of additional observed confounders, is in my opinion of high scientific quality, Professor Jewell has chosen to conduct a new analysis (of inferior scientific quality) of these data based solely on the exposed cohort and without the benefit of propensity score matching. In this analysis he has attempted to compare women who filled one or more prescriptions for Zoloft during their first trimester of pregnancy to women who filled a prescription for Zoloft who had a supply that carried into the 1st trimester but did not refill their prescription during the 1st trimester. While Huybrechts and colleagues define this latter group as an exposed group, Professor Jewell redefines this as a "paused" group. Note that this is a very different "paused group" than defined by Jimenez-Solem in which those women had not filled a prescription within three months of their pregnancy and therefore had no exposure to Zoloft during the 1st trimester. Indeed, in Professor Jewell's re-analysis, the "paused group" may have been the only group exposed during the earliest stages of pregnancy since by definition they are the only women in the exposed group that definitively had access to Zoloft at the start of their pregnancy. Those women who filled a prescription for Zoloft during their 1st trimester could have done so at any point in time during the 1st trimester, and there is nothing in the data to indicate that this was a refill of a prescription taken prior to pregnancy. As such, this is a very questionable definition of a control group and was never considered as a control group in the original analyses performed by Huybrechts and colleagues and reported in their paper.

21. Professor Jewell presented the following slide during his testimony at the Frye hearing which states that the number of Zoloft "paused" users is 2442. A search of the paper and appendices does not reveal the number "2442." From Table S18 from

the Appendix (see below) we know that there were 8,617 women with 92 cardiac events who filled one or more prescriptions for Zoloft during the 1st trimester.

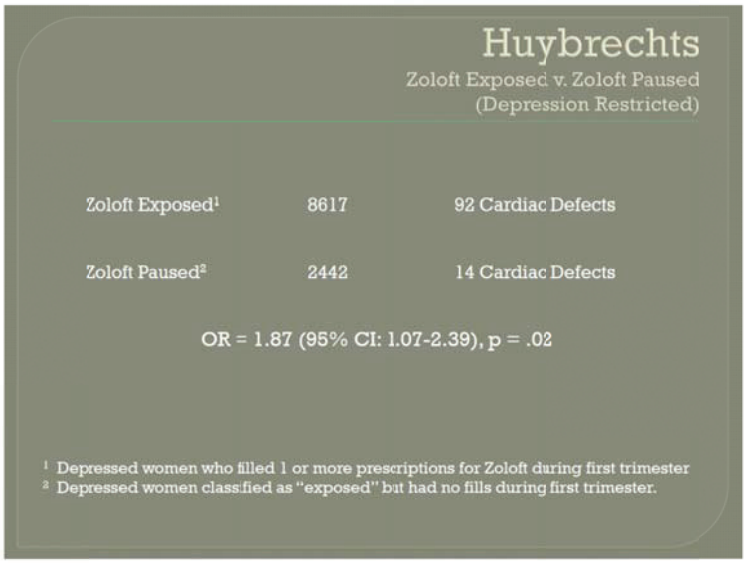


Table S18 Relative risks and 95% confidence intervals comparing the risk for cardiac malformations between exposed and unexposed women, varying the exposure definitions; restricted to women with depression diagnosis with PS adjustment. Medicaid Analytic eXtract 2000-2007.

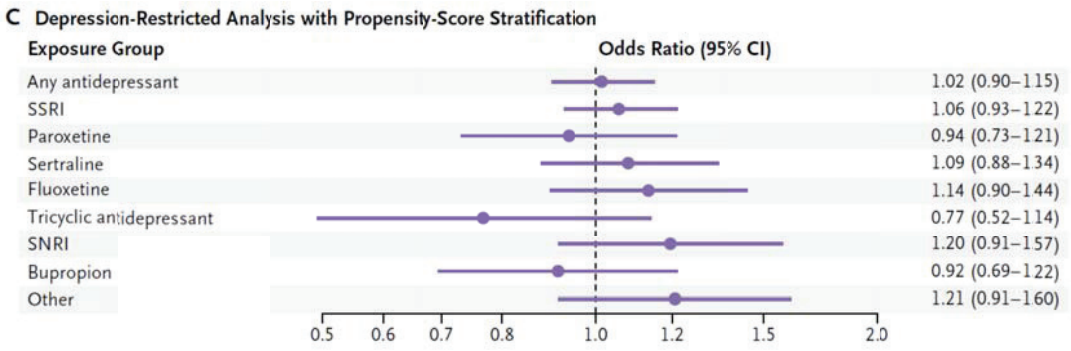
Exposure	N Patients		N Outcomes		OR (95% CI)
	Exp	Unexp	Exp	Unexp	
Exposed: ≥1 Dispensing during the first trimester					
ANTIDEP	29,056	181,164	282	1,503	1.09 (0.94, 1.26)
SSRI	28,168	181,164	270	1,503	1.11 (0.95, 1.29)
PAROXETINE	6,543	181,163	59	1,503	1.04 (0.79, 1.37)
SERTRALINE	8,617	181,164	92	1,503	1.19 (0.95, 1.49)
FLUOXETINE	6,660	181,164	60	1,503	1.06 (0.80, 1.40)
TCAS	2,281	181,157	19	1,503	0.78 (0.48, 1.25)
SNRIS	4,442	181,164	46	1,503	1.03 (0.75, 1.43)
BUPROPION	5,058	181,164	43	1,503	0.93 (0.67, 1.28)
OTHER	4,264	181,164	50	1,503	1.31 (0.95, 1.80)
Exposed: ≥2 Dispensings during the first trimester					
ANTIDEP	17,834	181,164	188	1,503	1.14 (0.95, 1.36)
SSRI	11,430	181,164	116	1,503	1.14 (0.92, 1.41)
PAROXETINE	2,602	181,152	28	1,503	1.24 (0.84, 1.84)
SERTRALINE	3,164	181,159	34	1,503	1.17 (0.82, 1.67)
FLUOXETINE	2,419	181,154	25	1,503	1.21 (0.80, 1.83)
TCAS	654	181,124	<11	1,502	0.93 (0.43, 2.02)
SNRIS	1,966	181,153	26	1,502	1.34 (0.87, 2.05)
BUPROPION	1,409	181,144	18	1,503	1.35 (0.82, 2.21)
OTHER	1,285	181,161	18	1,503	1.50 (0.90, 2.51)
Reference group: No exposure throughout pregnancy					
ANTIDEP	49,553	168,783	460	1,402	0.99 (0.87, 1.13)
SSRI	36,759	169,029	341	1,403	1.04 (0.91, 1.20)
PAROXETINE	8,757	169,028	71	1,403	0.92 (0.71, 1.20)
SERTRALINE	11,059	169,029	106	1,403	1.04 (0.84, 1.29)
FLUOXETINE	8,655	169,029	84	1,403	1.09 (0.86, 1.39)
TCAS	3,314	169,028	27	1,403	0.73 (0.49, 1.10)
SNRIS	6,009	169,029	69	1,403	1.11 (0.84, 1.47)
BUPROPION	6,697	169,029	57	1,403	0.87 (0.66, 1.17)
OTHER	6,006	169,029	64	1,403	1.15 (0.86, 1.53)

22. What Professor Jewell appears to have done is to subtract the number of women filling one or more prescriptions for Zoloft in the 1st trimester (8,617) from the bottom third of the Table which appears to represent the total cohort of exposed women compared to a restricted subset of the unexposed group which did not take any antidepressant throughout their pregnancy. This subtraction gives 11,059-8,617=2442 and for the number of events 106-92=14, which are the numbers that he reports in his slide and are the basis for his computed OR=1.87 (1.07, 2.39). Professor Jewell is also a plaintiff's expert in litigation concerning Prozac and birth defects, where he has opined that Prozac increases the risk of cardiac defects. If we follow his methodology using Table S18 data for Prozac, we find 60 events in 6660 women with one or more filled prescriptions in the 1st trimester and 24 events in 1995 "paused" women, yielding an OR=0.75 (0.45, 1.24) clearly violating his position that Prozac also significantly increases the risk of cardiac birth defects. Curiously, he has not provided such an analysis in that case.

23. Professor Jewell has also not conducted his new analysis separately for women who filled two or more prescriptions (see the middle section of Table S18) which would guarantee a refilled prescription during the 1st trimester. Had he done so he would have found that the rate of cardiac defects actually is lower (9.41 per 1,000) than for those women filling a single prescription (11.59 per 1,000) for which a subset may be the only prescription filled. If there really was an association, we would expect it to be more pronounced for women who were more consistently medicated during early pregnancy. In fact the reverse is true.

24. Had Professor Jewell conducted his new analysis for all antidepressant breakdowns, he would have found (applying his standard of disregarding statistical significance) that increased risks are not restricted to SSRIs, but also are found for "other" non-SSRI and non-SNRI antidepressants (OR=1.47, 95% CI=0.78, 2.78). In addition, as a class, SNRIs are also associated with decreased risk of cardiac birth defects (OR=0.71, 95% CI=0.42, 1.21). Using Professor Jewell's analysis, the class of SSRIs for which there are far more data available also show no association with cardiac birth defects (OR=1.16, 95% CI=0.89, 1.52). It seems very unlikely that SNRIs and Prozac decrease risk of birth defects and therefore it seems equally unlikely that

Zoloft increases birth defects. The more complete analysis performed by Huybrechts (2014) confirms the absence of an association with any antidepressant with similar odds ratios and broadly overlapping confidence intervals, indicating a lack of statistically meaningful difference in risk:



25. The data in lower portion of Table S18 do provide for an even cleaner comparison of exposed versus unexposed subjects, where for the unexposed group, they provide a subset of the controls who never took an antidepressant throughout their entire pregnancy and not just during the first trimester. Here the association between Zoloft and cardiac birth defects is again absent and even closer to the null value of 1.0 (OR=1.04, 95% CI=0.84, 1.29). This is an even more stringent definition of "unexposed" and rather than identifying a difference in incidence relative to exposed subjects, it clearly demonstrates the complete absence of such a difference.

26. It is curious that Professor Jewell does not rely on the published meta-analyses of Myles (2013) and McDonagh (2014), but does attempt to do his own putative "meta-analysis" of Jimenez-Solem and his post-hoc subgroup analysis of Huybrechts. The definitions of "paused" groups are quite different and meta-analysis of only a portion of the available data from only two studies with such different definitions is not methodologically proper. Among other methodological flaws, Professor Jewell's so-called meta-analysis, excluded most available data from the two studies which his analysis was based on, thereby failing to provide a complete and accurate synthesis of the available information. Meta-analysis by accepted, reliable methods, in contrast to

Dr. Jewell's putative meta-analysis, shows no association between Zoloft and cardiac defects. *See* Myles (2013) and McDonagh (2014).

27. The results of Professor Jewell's post-hoc analysis of the Huybrechts data appear anomalous in comparison with the reported findings of the study. Why would a comparison of the exposed cohort to a comparison group of depressed unexposed women find no difference, but a comparison of women filling a prescription in the 1st trimester to those women who filled a prescription shortly before their pregnancy (with enough pills to carry-over into the 1st trimester) provide a significant exposure effect with OR=1.87 (1.07, 2.39)? It just does not make sense. If there is a real association it should be the reverse in that the "paused" group is a mix of exposed and unexposed subjects so the true effect should be even larger, and not disappear as it does in Huybrechts' comparison of the depression restricted exposed versus unexposed cohort.

28. To better understand what is happening, let's dig a little deeper into the data. Let's define group A as the women in Professor Jewell's analysis who filled a prescription in the first trimester and group B as those women who he considers "paused." The exposed group in Huybrechts' analysis is therefore A+B. Finally, group C is the depression restricted cohort of unexposed women in Huybrechts' analysis. The rates of cardiac defects for the various groups are as follows:

    Group A – Filled a prescription in 1st trimester – 92/8617=1.07%

    Group B – Exposed but no prescription filled in 1st trimester – 14/2442=0.57%

    Group A+B – Huybrechts' exposed group – 106/11059=0.96%

    Group C – Huybrechts' unexposed depressed cohort – 1497/180,564=0.83%

29. The simple unadjusted comparison of groups A and B which represents Professor Jewell's post-hoc analysis RR=1.07/0.57=1.88 confirms his OR=1.87 computation, the small difference due to rounding and RR versus OR. Similarly, comparison of A+B versus C yields RR=0.96/0.83=1.16 which confirms Huybrechts' unadjusted depression restricted comparison. However, what is new here is that Dr. Jewell's finding is explained, not by an increased risk in the group that refilled prescriptions

during the first trimester, but by an anomalously low rate of defects in the group Dr. Jewell chose to designate as "paused." In fact, the rate of cardiac defects in depressed women who did not fill any prescription was actually 45% higher than women who filled a prescription just before the 1st trimester of their pregnancy (OR=1.45, 95% CI 0.84, 2.56). This suggests that if we believe Professor Jewell's analysis, the best way to decrease the rate of cardiac birth defects is to prescribe Zoloft to women trying to get pregnant, in sufficient supply to carry over into their 1st trimester of pregnancy. This of course is ridiculous and nicely illustrates the dangers of post-hoc analyses and the fallacies that occur with repeated dissection of the data into meaningless subgroups, which is what Professor Jewell has done.

30. All of the opinions I offer are given to a reasonable degree of scientific certainty.

Summary and Conclusions

31. The best available data do not support an association between Zoloft exposure in the 1st trimester of pregnancy and cardiac birth defects. Without an association any discussion of causation is misguided. It is unclear why Professor Jewell conducted the analysis that he did, and it is methodologically flawed for the reasons stated above. The analysis performed and published by the original authors was far more rigorous in that it eliminated the possibility of exposure in the 1st trimester whereas Professor Jewell's analysis did not. He suggests that this is conservative since a comparison to unexposed depressed mothers would then show an even larger effect. Of course, this is the analysis performed by Huybrechts (2014) in the first place and the effect was much smaller rather than larger than the analysis performed by Professor Jewell. The analysis performed by Professor Jewell is inferior to the one performed by the original authors because it does not compare exposed (during the 1st trimester) and unexposed mothers with depression and does not include adjustment for the remaining imbalance in the distributions of potential confounders. Finally, when we dig a little deeper, we find that the inconsistent results between Professor Jewell's post-hoc comparison and Huybrechts' analysis is produced by his "paused" group having a substantially lower rate of cardiac birth defects than untreated

depressed women, a result which makes no sense whatsoever and is likely due to chance produced by post-hoc subgroup analyses.

Dated March 27, 2015

Robert D. Gibbons, PhD

Appendix A

CURRICULUM VITAE

ROBERT D. GIBBONS

PERSONAL INFORMATION

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Date of Birth: June 28, 1955
Place of Birth: Chicago IL
Citizenship: U.S.

EDUCATION AND TRAINING

Ph.D., University of Chicago, 1981, Statistics and Psychometrics.

Dissertation Topic: Trend in Correlated Proportions
Dissertation Committee: R. Darrell Bock, James J. Heckman, David L. Wallace, James S. Coleman

B.A., University of Denver, 1976, Chemistry and Mathematics

PROFESSIONAL/ACADEMIC APPOINTMENTS:

2010-present Director, *Center for Health Statistics*, University of Chicago.
2010-present Professor of Medicine, University of Chicago.
2010-present Professor of Public Health Sciences, University of Chicago.
2010-present Professor of Psychiatry, University of Chicago.
2010-present Professor Emeritus of Biostatistics, University of Illinois
2009-2010 Professor of Mathematics, Statistics and Computer Science, UIC.
2000-2010 Director, *Center for Health Statistics*, University of Illinois at Chicago.
1993-2010 Professor of Biostatistics, University of Illinois at Chicago.
1993-2010 Professor of Psychiatry, University of Illinois at Chicago.
1985-1993 Associate Professor of Biostatistics, University of Illinois at Chicago.
1985-1993 Associate Professor of Psychiatry, University of Illinois at Chicago.
1988-1989 Visiting Professor, University of Chicago.
1981-1985 Assistant Professor of Biostatistics, University of Illinois at Chicago.
1981-1985 Assistant Professor of Psychiatry, University of Illinois at Chicago.
1981-1986 Statistical Consultant, National Institute of Mental Health.
1980-1981 Senior Programmer and Statistician, University of Chicago, DOD/NORC.
1978-1982 Statistician, Illinois State Psychiatric Institute.
1978-1980 Statistical Consultant, Harvard University, Department of Psychology.
1977-1978 Statistical Analyst, University of Chicago, Department of Psychiatry.

HONORS, AWARDS, SCHOLARSHIPS

Scholarship for Graduate Study, 1978-1981, University of Chicago
Young Investigator Award, 1985-1992, Office of Naval Research
Research Scientist Award - National Institute of Mental Health, 1995-2000
20th Century Distinguished Service Award for Outstanding Contribution to the Development of Statistical Ecology, Environmental Statistics and Risk Assessment, 2000
Fellow of the American Statistical Association, 2001
Member of the Institute of Medicine of the National Academy of Sciences, 2001
Member of the American College of Neuropsychopharmacology, 2001
Youden Prize for Contributions to Inter-laboratory Calibration (ASA, 2002)
Harvard Award in Psychiatric Epidemiology and Biostatistics, (Harvard, 2003)
2001 Book with Coleman ranked in the top 5 books for Statisticians by the ASA
Youden Prize for Contributions to Inter-laboratory Calibration (ASA, 2006)
University of Illinois at Chicago - Distinguished Faculty Award, 2009
American Statistical Association – Outstanding Statistical Applications Award, 2009
Professor Emeritus of Biostatistics, University of Illinois, 2010
Pritzker Scholar, University of Chicago, 2011
Rema Lapouse Award for Contributions to Psychiatric Epidemiology – APHA, 2012
Long-Term Excellence Award – Health Policy Statistics Section – ASA, 2013
Advisor to the Director of NIH (Dr. Francis Collins), 2014

PROFESSIONAL MEMBERSHIPS

Institute of Medicine of the National Academy of Sciences
American Statistical Association (Fellow)
Biometric Society
Psychometric Society
American College of Neuropsychopharmacology
Institute of Medicine of Chicago

REVIEW AND EDITORIAL EXPERIENCE

Reviewer for *Journal of American Statistical Assoc.*, *Biometrics*, *Psychometrika*, *Technometrics*, *Archives of General Psychiatry*, *Journal of Psychiatric Research*, *American Journal of Psychiatry*, *Science*, *Psychiatry Research*, *Sociological Methodology*, *Psychological Bulletin*, *Biological Psychiatry*, *Environmental Science and Technology*, *Statistics in Medicine*, and *Ground Water.*

Grant reviewer for National Institute of Mental Health
Editorial Board of *Health Services and Outcomes Research*
National Institute of Mental Health Services Research IRG Member 1992-1996
Veterans Administration Cooperative Study Review Board, 1998
Editorial Board of *JAMA Psychiatry*

ADMINISTRATIVE/COMMITTEE WORK

Institute of Medicine - Committee on the Drug Halcion, 1997
Institute of Medicine - Committee on Organ Procurement and Transplantation Policy, 1999
Institute of Medicine - Health Sciences Policy Board Member, 1999-2004.
Institute of Medicine - Committee on Small *n* Clinical Trials, 2001
Institute of Medicine - Committee on Adolescent and Adult Suicide, 2002
FDA Advisory Board on Suicide and Antidepressants in Adolescents, 2004
Institute of Medicine - Committee on National Cord Blood Stem Cell Program, 2005
Institute of Medicine - Committee on US Drug Safety, 2005-2006
NIH Consensus Panel on the Efficacy and Safety of Multivitamins, 2006
VA – Blue Ribbon Working Group on Suicide Prevention in the Veterans Population, 2008
Institute of Medicine/NRC – Asbestos Research Roadmap Committee, 2009
National Academy of Sciences/NRC – Committee on Assessment of Agent Monitoring Strategies for the Blue Grass and Pueblo Chemical Agent Destruction Pilot Plants, 2011
Mathematica Panel on Performance Measure Testing, 2013

RECENT KEY PRESENTATIONS

Congressional Testimony on *Allocation of Organs for Transplantation* (on behalf of the National Academy of Sciences) - 9/21/99.

Biological Psychiatry Meeting. *The Statistics of Suicide*, 2008.

Harvard University Department of Statistics. *Statistical Issues in Drug Safety: The Curious Case of Antidepressants, Anticonvulsants, ... , and Suicide*, 2008.

Great Lakes cGMP & Regulatory Science Forum. *Post-Approval Drug Safety Surveillance*, 2009.

International Symposium about Current Issues and Controversies in Psychiatry. *The Curious Case of Antidepressants, Anticonvulsants, ... , and Suicidal Behavior*, 2009.

University of Chicago Health Economics Meetings. Discussion of *A Flexible Two-part Random Effects Model for Correlated Medical Costs*, 2009.

Institute of Medicine - Co-Chair – *CNS Clinical Trials: Suicidality and Data Collection*, 2009.

International Conference on Health Policy Statistics. *Statistical Issues in Drug Safety*, 2010.

New Clinical Drug Evaluation Unit (NCDEU) meeting: *The Future of Psychiatric Measurement*, 2010.

NCDEU meeting: *Post Approval Drug Safety Surveillance*, 2010.

APHA Annual Meeting: *Rema Lapouse Award Lecture*, 2012.

IASR World Congress of Suicide, Keynote Speaker, 2013

American Statistical Society: International Conference on Health Policy Statistics, Keynote Speaker 2013.

RECENT TEACHING EXPERIENCE AND CURRICULUM DEVELOPMENT

University of Illinois at Chicago – Division of Biostatistics – Guest lecturer – 2000-2010

Longitudinal Data Analysis (#537)
Logistic Regression and Survival Analysis (#505)
Biostatistics Research Seminar (#595).
PGY-3 Research Methods in Psychiatry

University of Chicago – 1988-1989

Multivariate Statistics (Division of Social Sciences)

University of Chicago – 2012-2013

Statistical Applications (Health Studies)

MENTORSHIP

University of Chicago

Ph.D.

Eiji Muraki (1983) *Marginal maximum likelihood estimation for three-parameter polychotomous item response models: application of an EM algorithm*.

Ulf Bockenholt (1985) *Inverse prediction in behavioral research.*

Donald R. Hedeker (1989) *Random Regression models with autocorrelated errors: investigating drug plasma levels and clinical response.*

Steven G. Schilling (1993) *Advances in full-information factor analysis using the Gibbs sampler.*

Matthew Churpek (2014) Predicting in-hospital cardiac arrest using electronic health record data.

Marcelo Coca Perraillon (in progress)

University of Illinois at Chicago

Ph.D.

Subhash Aryal: (2008) *Small sample tests and sample size determination for linear and non-linear mixed-effects models.*

Kush Kapur (2010) *Hypothesis testing, power and sample size determination for health science data.*

Anup Amatya (2011) *Meta analysis for binary adverse event data.*

Yoonsang Kim: (2011) *Confidence and prediction intervals for small sample asbestos fiber counts.*

Glen Schumock (2012) *Drug Safety*

David Morton: (2015) *Hospital Profiling*

M.S.

Subhash Aryal: (2004)

Arijit Sinha (2006)

Anup Amatya (2007)

Post-Doctoral Fellowship

Jason Immekus (2008)

FUNDED RESEARCH

Current:

2013-2018 National Institute of Mental Health. *A New Statistical Paradigm for Measuring Psychopathology in Youth*, Administrative Supplement, $600,000 (PI).

2013-2018 National Institute of Mental Health. *A New Statistical Paradigm for Measuring Psychopathology in Youth*, Grant #RO1 MH100155-01, $3,376,000 (PI).

2014-2018 National Institute of Mental Health. *Risks and Benefits of ADHD Medication for Psychiatric and Neurologic Problems* (D'Onofrio). R01 MH102221, (PI of Statistical Core).

2014-2017 NIH/PECARN. *Emergency Department Screen for Teens at Risk for Suicide (ED-STARS)*. U01MH104311 (King), (PI or Statistical Core).

2011-2016 National Institute of Health (AHRQ - CERT). *Tools for Optimizing Prescribing, Monitoring and Education.* U18HS016973 (Lambert), $4,000,000, (PI of Statistical Core).

2011-2016 CMS. *Integrated Inpatient and Outpatient Care for Patients at High Risk of Hospitalization*. 1C1CMS331033-01-01 (Meltzer), (PI of Statistical Core).

Past:

1984-1985 Campus Research Board of the University of Illinois. Grant #889 *Statistical Models of Complex Psychiatric Data.* $10,300 (PI)

1985-1988 Office of Naval Research. Young Investigator Award. *Conditional Dependence*, $181,000 (PI).

1986-1987 National Institute of Mental Health. *A Comparison of Discrete and Continuous Latent Structure*, Grant #1RO3 MH 39750-01 A1 $15,000, 1986 (Co. PI).

1985-1987 MacArthur Foundation, Network I, *Biometric Laboratory Support* $150,000 (PI).

1988-1989 Campus Research Board of the University of Illinois. Grant #5590 *Statistical Visualization*. $8,000 (PI).

1988-1990 MacArthur Foundation, Network I, *A Statistical Model for Biological Rhythm Study* $30,000 (PI).

1988-1991 Office of Naval Research. Continuation of Support for *Conditional Dependence*, $184,000 (PI).

1990-1992 National Institute of Mental Health. *Problem Drinking Over Time by Future MDs* Grant # RO1 AA07311-05, $493,233, Statistician, (Dr. Judy Richman PI).

1990-1991 MacArthur Foundation, Network I, *Social Zeitgebers and Biological Rhythms* $24,000. (Co. PI).

1990-1991 National Institute of Mental Health. *MIXMASTER: A computer program for resolving normal mixtures*, Grant #R43 MH 45620-01 A1 $50,000, (PI).

1991-1995 National Institute of Mental Health. *Statistical Evaluation: Preschoolers Behavior Problems & Health Care Use: A Longitudinal Study*, Grant # RO1 MH46089, $154,603, (Biostatistical Subcontract - Dr. John Lavigne PI).

1991-1993 National Institute of Mental Health. *Random Regression Models for Longitudinal Psychiatric Data*, Grant #RO1 MH 44826-01 A2 $299,000, (PI).

1991-1992 National Institute of Mental Health. *Monoamine Receptor Sensitivity in Mental Illness*, Grant #RO1 MH36169-08A2, $187,040, Statistician, (Dr. Ghanshyam PI).

1991-1992 MacArthur Foundation, Network I, *A Statistical Re-evaluation of the NIMH Treatment Collaborative Study of Depression Using Random Regression Models*, $34,167. (PI).

1992-1997 National Institute of Mental Health. *Schizophrenic Cognition: A Longitudinal Study*, Grant # HHS-2 RO1 MH26341-17, $36,000 Biostatistical subcontract, (Dr. Martin Harrow PI).

1992-1996 National Institute of Mental Health. *Serotonin Receptors in Teenage Suicide and Their Families*, Grant # RO1 MH48153-01A1, $940,316, Statistician, (Dr. Ghanshyam Pandey PI).

1993-1996 National Institute of Mental Health. *Random Regression Models for Longitudinal Psychiatric Data*, Grant #RO1 MH 44826-03 A1 $473,080, (PI). Renewal

1995-2000 National Institute of Mental Health. *Research Scientist Award* Grant #K05 MH01254 $458,132

(PI).

1996-2000 National Institute of Mental Health. *Statistical Models for Nested Service Utilization Data* Grant #RO1 MH 56146 $473,080 (CO-PI) (Dr. Donald Hedeker PI).

2000-2004 National Institute of Mental Health. *Statistical Models for Nested Service Utilization Data* (percentile = 0.5) Grant #RO1 MH 56146-04 $1,233,936 (CO-PI) (Dr. Donald Hedeker PI).

2000-2007 National Institute of Mental Health. *Statistical Center for the MTA Follow-up Study*, $923,000 (PI).

2002-2007 National Institute of Mental Health. *Mixed-effects ZIP models for Mental Health Services Research*, #RO1 MH65556-01, $660,735 (PI).

2002-2006 National Institute of Mental Health. *Mental Health Computerized Adaptive Testing*, Grant #RO1 MH66302-01, $1,077,502 (PI).

2004-2007 National Institute of Mental Health. *Multivariate Probit Model for Health Services Research*, Grant #RO1 MH67198-01, $663,950 (Dr. Hua Yun Chen PI).

2005-2008 National Institute of Mental Health. *Statistical Testing for Generalized Mixed-effects Models*, Grant #RO1 MH069353, $450,000 (Dr. Dulal Bhaumik PI).

2005-2006 National Cancer Institute. *Evaluation of the Added-Value of Multidimensional and Hierarchical Psychometric Modeling for Cancer Outcomes*, Contract #05828, $150,000 (PI).

2006-2007 National Institute of Mental Health. *Antidepressant Treatment and Suicidality: Methodological and Biostatistical Solutions. #R56* MH078580-01, $232,500 (PI).

2007-2011 National Institute of Health (AHRQ - CERT). *Tools for Optimizing Prescribing, Monitoring and Education.* U18HS016973, $4,000,000 (PI of Statistical Core).

2006-2013 National Institute of Mental Health. *Mental Health Computerized Adaptive Testing - Competitive Renewal*, Grant #RO1 MH66302-04, $3,429,658 (PI).

2007-2013 National Institute of Mental Health. *Autism Center of Excellence: Translational Studies of Insistence of Sameness in Autism.* 1P50HD055751, $9,600,000 (PI of Statistical Core).

2008-2013 National Institute of Mental Health. *Antidepressant Treatment and Suicidality: Methodological and Biostatistical Solutions. #R01* MH8012201, $2,640,000 (PI).

2009-2013 National Institute of Mental Health. *Mental Health Computerized Adaptive Testing - Supplement*, Grant #RO1 MH66302-04, $1,773,298 (PI).

PUBLICATIONS (peer reviewed, by topic area – authors are current or former students or trainees)

General Statistics and Biostatistics:

1. **Gibbons R.D.**, Fielder-Weiss V.C., West D.P., Lapin G. Quantification of scalp hair - a computer aided methodology. *Journal of Investigative Dermatology, 86*, 78-82, 1986.
2. **Gibbons R.D.,** Computer-aided quantification of scalp hair. *Dermatologic Clinics, 4*, 627-640, 1986.
3. **Gibbons R.D.**, Bock RD. Trend in Correlated Proportions. *Psychometrika, 52*, 113-124, 1987.
4. Hatoum N.S., Leach C.L., Talsma D.M., **Gibbons R.D.**, & Garvin P.J. A statistical basis for using

fewer rabbits in dermal irritation testing. *Journal of the American College of Toxicology*, *9*, 49-60, 1990.

5. Tanner J.M., **Gibbons R.D.** & Bock R.D. An image analysis system for TW skeletal maturity. *Hormone Research*, *32*, 11, 1992.
6. **Gibbons R.D.**, Hedeker D.R. & Davis J.M. Estimation of effect size from a series of experiments involving paired comparisons. *Journal of Educational Statistics*, *18*, 271-279, 1993.
7. **Gibbons R.D.**, Hedeker D.R. Charles S.C., & Frisch P. A random-effects probit model for predicting medical malpractice claims. *Journal of the American Statistical Association*, *89*, 760-767, 1994.
8. Tanner J.M., & **Gibbons R.D.** A computerized image analysis system for estimating Tanner-Whitehouse 2 bone age. *Hormone Research*, *42*, 282-287, 1994.
9. Hedeker D.R., & **Gibbons R.D.** A random-effects ordinal regression model for multilevel analysis. *Biometrics*, *50*, 933-944, 1994.
10. Tanner J.M., & **Gibbons R.D.** Automatic bone age measurement using computerized image analysis. *J. Paed Endocr*, *7*, 141-145, 1994.
11. Hedeker D. & **Gibbons R.D.** MIXOR: a computer program for mixed-effects ordinal regression analysis. *Computer Methods and Programs in Biomedicine*, *49*, 157-176, 1996.
12. Hedeker D. & **Gibbons R.D.** MIXREG: a computer program for mixed-effects regression analysis with autocorrelated errors. *Computer Methods and Programs in Biomedicine*, *49*, 229-252, 1996.
13. Bock R.D. & **Gibbons R.D.** High dimensional multivariate probit analysis. *Biometrics*, *52*, 1183-1194, 1996.
14. Hedeker D. & **Gibbons R.D.** Application of random-effects pattern-mixture models for missing data in longitudinal studies. *Psychological Methods*, *2*, 64-78, 1997.
15. **Gibbons R.D.** & Hedeker D. Random-effects probit and logistic regression models for three-level data. *Biometrics*, *53*, 1527-1537, 1997.
16. **Gibbons R.D.** & Wilcox-Gök V. Health Service Utilization and Insurance Coverage: A Multivariate Probit Analysis. *Journal of the American Statistical Association*, *93*, 63-72, 1998.
17. **Gibbons R.D.** & Lavigne J.V. Emergence of childhood psychiatric disorders: A multivariate probit analysis. *Statistics in Medicine*, *17*, 2487-2499, 1998.
18. Hedeker D.R., **Gibbons R.D** & Waternaux C. Sample size estimation for longitudinal designs with attrition. *J. of Educational Statistics*, *24*, 70-93, 1999.
19. **Gibbons R.D.**, Brown B.W., Azarnoff D.L., Bunney W.E., Cancro R., Gillin J.C., Hullett S., Killam K.F., Krystal J.H., Kupfer D.J., Stolley P.D., Pope A.M., French G.S. Assessment of the safety and efficacy data for the hypnotic Halcion$^{(R)}$: Results of an analysis by an Institute of Medicine committee. *Journal of the American Statistical Association*, *94*, 993-1002, 1999.
20. **Gibbons R.D.**, Meltzer D., Duan N., Penhoet E.D., Dubler N.N., Francis C.K., Gill, B., Guinan E., Henderson M., Ildstad S.T., King, P.A., Martinez-Maldonado M., Mclain G.E., Murray J.E., Nelkin D. Spellman M.W, Pope A. and Pitluck S. Waiting for Organ Transplantation, *Science*, *287*, 237-238, 2000.
21. **Gibbons R.D.**, Duan, N., Meltzer D. Inequities in liver transplant allocation. *Science*, *289*, 549, 2000.
22. **Gibbons R.D.** & Hedeker D. Applications of mixed-effect models in biostatistics. *Sankhya*, *62*, Series B, 70-103, 2000.
23. Marcus S.M. and **Gibbons R.D.** Estimating the Efficacy of Receiving Treatment In Randomized Clinical Trials with Noncompliance. *Health Services and Outcomes Research Methodology*, *2*,

247-258, 2001.

24. **Gibbons R.D.**, Duan N., Meltzer D., Pope, A., Penhoet E.D., Dubler N.N., Francis C.K., Gill, B., Guinan E., Henderson M., Ildstad S.T., King, P.A., Martinez-Maldonado M., Mclain G.E., Murray J.E., Nelkin D. Spellman M.W, and Pitluck S. Waiting for Organ Transplantation: Results of an analysis by an Institute of Medicine Committee, *Biostatistics*, *4*, 207-222, 2003.
25. **Gibbons R.D.** Racial disparities in liver transplantation. *Liver Transplantation*, *10*, 842-843, 2004.
26. **Gibbons R.D.**, Lazar N.A., Bhaumik D.K., Sclove S.L., Chen H.Y., Thulborn K.R., Sweeney J.A., Hur K., Patterson D. Estimation and classification of fMRI hemodynamic response patterns. *Neuroimage*, *22*, 804-814, 2004.
27. **Gibbons R.D.**, Bhaumik, D.K., Cox D.R., Grayson D., Davis J.M., and Sharma R.P. Sequential Prediction Bounds for Identifying Differentially Expressed Genes in Replicated Microarray Experiments. *Journal of Statistical Planning and Inference*, *129*, 19-37, 2005.
28. Roy A., Bhaumik D.K., Aryal S., **Gibbons R.D.** Sample size determination for hierarchical longitudinal designs with differential attrition rates. *Biometrics, 63*, 699-707, 2007.
29. **Gibbons R.D.**, Hur K., Bhaumik D., Bell C.C. Profiling of county-level foster care placements using random-effects Poisson regression models. *Health Services and Outcomes research Methodology*, *7*, 97-108, 2007.
30. Aryal S., Bhaumik D.K., Mathew T. and **Gibbons R.D.** Approximate Tolerance Limits and Prediction Limits for the Gamma Distribution. *Journal of Applied Statistical Science*, *16*, 103-111, 2007.
31. **Gibbons R.D.**, Segawa E., Karabatsos G., Amatya A.K., Bhaumik D.K., Brown C.H, Kapur K., Marcus S., Hur K., Mann J.J. Random-effect Poisson regression analysis of adverse event reports: The relationship between antidepressants and suicide. Statistics in Medicine, 27, 1814-1833, 2008.
32. Bhaumik D.K., Roy A., Lazar N.A., Kapur K., Aryal S., **Gibbons R.D.**, Sweeney J.A., Patterson D: Hypothesis testing, power and sample size determination for between group comparisons in fMRI experiments. *Statistical Methodology*, 6, 133-146, 2008
33. **Gibbons R.D**. Design and analysis of longitudinal studies. *Psychiatric Annals*, 38, 758-761, 2008.
34. Bhaumik D.K., Roy A. Aryal S., Hur K., Duan N., Normand S.L.T., Brown C.H., **Gibbons R.D.** Sample size determination for studies with repeated continuous outcomes. *Psychiatric Annals*, 38, 765-771, 2008.
35. Lavori P.W., Brown C.H., Duan N., **Gibbons R.D.**, Greenhouse J. Missing data in longitudinal clinical trials - Part A: Design and conceptual issues. *Psychiatric Annals*, 38, 784-792, 2008.
36. Siddique J., Brown C.H., Hedeker D., Duan N., **Gibbons R.D.**, Miranda J., Lavori P.W. Missing data in longitudinal trials – Part B: Analytic issues. *Psychiatric Annals*, 38, 793-801, 2008.
37. Marcus S.M., Siddique J., Ten Have, T.R., **Gibbons R.D.**, Stuart E., Normand S.L.T. Balancing treatment comparisons in longitudinal studies. *Psychiatric Annals*, 38, 805-811, 2008.
38. Brown C.H., Ten Have T.R., Jo B., Dagne G., Wyman P.A., Muthén B., and **Gibbons R.D.** Adaptive designs in public health. *Annual Review of Public Health*, 30, 17.1-17.25, 2009.
39. Bhaumik D.K., Kapur K., **Gibbons R.D.** Testing parameters of a gamma distribution for small samples. *Technometrics*, 51, 326-334, 2009.
40. Kapur K., Roy A., Bhaumik D.K., **Gibbons R.D.**, Lazar N.A., Sweeney J.A., Aryal S., Patterson D. Estimation and classification of BOLD responses over multiple trials. *Communications in Statistics*, 38, 3009-3113, 2009.
41. Bhaumik D.K., Santra S., Aryal S., **Gibbons R.D.** One-sided simultaneous prediction limits for left censored normal random variables. Sankhya (Series B), 70, 226-282, 2009.

42. Kraemer H.C., **Gibbons R.D.** Where do we go wrong in assessing risk factors, diagnostic and prognostic tests? The problems of two-by-two association. *Psychiatric Annals*, 39, 711-718, 2009.

43. Kraemer H.C., **Gibbons R.D.** Why does the randomized clinical trial methodology so often mislead clinical decision-making? Focus on moderators and mediators of treatment. *Psychiatric Annals*, 39, 736-745, 2009.

44. Teixeira-Pinto A., Siddique J., **Gibbons R.D.**, and Normand S.L.T. Statistical approaches to modeling multiple outcomes in psychiatric studies. *Psychiatric Annals*, 39, 711-718, 2009.

45. Stuart E.A., Marcus S.M., Horvitz-Lennon M.V., **Gibbons R.D.**, Normand S.L.T., Brown C.H. Using non-experimental data to estimate treatment effects. *Psychiatric Annals*, 39, 719-728, 2009.

46. **Gibbons R.D.** Design and analysis of longitudinal studies, part 2., *Psychiatric Annals*, 39, 690-691, 2009.

47. **Gibbons R.D.**, Hedeker D., DuToit S. Advances in analysis of longitudinal data. *Annual Review of Clinical Psychology*, 6, 79-107, 2010.

48. **Gibbons R.D.**, Amatya A.K., Brown C.H., Hur K., Marcus S.M., Bhaumik D.K., Mann, J.J. Post-approval drug safety surveillance. *Annual Review of Public Health*, 31, 419-437, 2010.

49. **Gibbons R.D.**, Lambert B.L., Mann J.J. A comment on Patorno et.al. (2010): Anticonvulsant medications and the risk of suicide, attempted suicide, or violent death. *JAMA*, 304, 521-522, 2010.

50. Siddique J., Crespi C.M., **Gibbons R.D.,** Green B.L. Using latent variable modeling and multiple imputation to calibrate rater bias in diagnosis assesment. *Statistics in Medicine*, 30, 160-174, 2011.

51. **Gibbons R.D.,** Mann J.J. Strategies for quantifying the relationship between medications and suicidal behavior: what has been learned. *Drug Safety*, 34, 375-395, 2011.

52. Bhaumik D.K., Aryal S., Amatya A., Kapur K., **Gibbons R.D.** Sample size determination for between group comparisons in mixed-effects logistic regression models for analysis of longitudinal data. *Journal of Applied Statistical Science*, 19, 1, 2011.

53. Bhaumik D.K., Amatya A., Normand S.L., Greenhouse J, .Kaizar E., Neelon B., **Gibbons R.D.** Meta-analysis of rare binary adverse event data. *Journal of the American Statistical Association*, 107, 555-567, 2012.

54. Marcus, S.M. and **Gibbons R.D.** Caution should be used in applying propensity scores estimated in a full cohort to adjust for confounding in subgroup analyses. *Pharmacoepidemiology and Drug Safety*, 21, 710-712, 2012.

55. Brown C.H., Mohr, D.C., Gallo C.G., Mader C., Palinkas L., Wingood Gina., Prado G., Kellam S.G., Pantin Hilda., Poduska J., **Gibbons R.D.,** McManus J., Ogihara M., Valente T., Wulczyn F., Czaja S., Sutcliffe G., Villamar J., Jacobs C. A Computational Future for Preventing HIV in Minority Communities: How Advanced Technology Can Improve Implementation of Effective Programs. *Journal of Acquired Immune Deficiency Syndromes*. 63:S72-S84, 2013.

56. Amatya A., Bhaumik D.K., **Gibbons R.D.** Sample size determination for clustered count data. *Statistics in Medicine*, 17, 162–4179, 2013.

57. Aryal S., Bhaumik D.K., Mathew T., **Gibbons R.D.** An optimal test for variance components of multivariate mixed-effects linear models. *Journal of Multivariate Analysis*, 124, 166-178, 2014.

58. Bhaumik D.K., Kapur K., Balakrishnan N., Keating J.P., **Gibbons R.D**. Small sample tests for

shape parameters of gamma distributions. *Communications in Statistics*, 44, 1339-1363, 2015.

59. **Gibbons, R.D.**, Coca-Perraillon, M., Kim, J.B. Item response theory approaches to harmonization and research synthesis. *Health Services and Outcomes Research Methodology*, 14, 213-231, 2014.
60. **Gibbons, R.D.**, Coca-Perraillon, M., Hur, K., Conti, R.M., Valuck, R.J., Brent, D.A. Antidepressant treatment and suicide attempts and self-inflicted injury in children and adolescents. *Pharmacoepidemiology and Drug Safety*, published on-line, 2014.
61. Amatya A., Bhaumik D.K., Normand S.L., Greenhouse J., Kaiser E., Neelon B., **Gibbons R.D.** Likelihood-based random effect meta-analysis of binary events. *J. of Biopharmaceutical Statistics*, published on-line, 2014.

Mental Health Statistics:

62. **Gibbons R.D.**, Clark, D., & Davis J.M. A statistical model for the classification of imipramine response in depressed inpatients. *Psychopharmacology, 78*, 185-189, 1982.
63. **Gibbons R.D.**, Dorus E., Ostrow D.G., Pandey G.N., Davis J.M., Levy D.L. Mixture distributions in psychiatric research. *Biological Psychiatry, 19*, 483-509, 1984.
64. **Gibbons R.D.**, Davis J.M. The price of beer and the salaries, of priest: a note on the analysis and display of longitudinal psychiatric data. *Archives of General Psychiatry, 41*, 1183-1184, 1984.
65. **Gibbons R.D.**, Lewine R.R.J., Davis J.M., Schooler N.R., Cole J.O. An empirical test of a Kraepelinian versus a Bleulerian view of negative symptoms. *Schizophrenia Bulletin, 11*, 390-395, 1985.
66. **Gibbons R.D.**, Maas J.W., Davis J.M., Swann A., Redmond E., Casper R., Hanin I., Bowden C., Kocsis J., Stokes P. Path analysis of psychopharmacological data: catecholamine breakdown in man. *Psychiatry Research, 18*, 89-105, 1986.
67. **Gibbons R.D.**, Davis J.M. Consistent evidence for a biological subtype of depression characterized by low CSF monoamine levels. *Acta Psychiatrica Scandinavica, 74*, 8-12,1986.
68. Gibbons R.D., Hedeker D., Davis J.M. Regression toward the mean: More on the price of beer and the salaries of priests. *Psychoneuroendocrinology, 12*, 185-192, 1987.
69. **Gibbons R.D.**, Janicak P.G., Davis J.M. A response to Overall and Rhoades regarding their comment on the efficacy of unilateral vs bilateral ECT. *Convulsive Therapy 3*, 228-237, 1987.
70. Davis J.M., Koslow S.H., **Gibbons R.D.**, Maas J.W., Bowden C.L., Casper R., Hanin I., Javaid J.I., Chang S.S., Stokes P.E. Cerebrospinal fluid and urinary biogenic amines and metabolites in depressed and healthy controls: a multivariate analysis. *Archives of General Psychiatry*, *45*, 705-717, 1988.
71. Clark D.C., & **Gibbons R.D.** Does one nonlethal suicide attempt increase the risk for a subsequent nonlethal attempt? *Medical Care*, *25*, 87-88, 1987.
72. Kraemer H.C., Pruyn J.P., **Gibbons R.D.**, Greenhouse J.B., Grochocinski V.J., Waternaux C., & Kupfer D.J. Methodology in psychiatric research. *Archives of General Psychiatry*, *44*, 1100-1106, 1987.
73. **Gibbons R.D.**, Hedeker D.R., Waternaux C., & Davis J.M. Random regression models: A comprehensive approach to the analysis of longitudinal psychiatric data. *Psychopharmacological Bulletin*, *24*, 438-443, 1988.
74. Hedeker D.R., **Gibbons R.D.**, Waternaux C., & Davis J.M. Investigating drug plasma levels and clinical response using random regression models. *Psychopharmacological Bulletin*, *25*, 227-

231, 1989.

75. Clark D.C., **Gibbons R.D.**, Fawcett, J. & Sheftner W.A. What is the mechanism by which suicide attempts predispose to later suicide attempts? A mathematical model. *Journal of Abnormal Psychology*, *98*, 1989.

76. **Gibbons R.D.**, Hedeker D.R. & Davis J.M. A comment on the selection of "healthy controls" for psychiatric experiments. *Archives of General Psychiatry*, *47*, 785-786, 1990.

77. **Gibbons R.D.**, Clark D.C & Fawcett J. A statistical method for evaluating suicide clusters and implementing cluster surveillance. *American Journal of Epidemiology, 132*, S183-S191, 1990.

78. Fawcett J., Sheftner W.A., Fogg L., Clark D.C., Young M.A., Hedeker D.R., & **Gibbons R.D.** Time-related predictors of suicide in major affective disorder. *American Journal of Psychiatry*, *147*, 1189-1194, 1990.

79. Hedeker D.R., **Gibbons R.D.**, & Davis J.M. Random regression models for multicenter clinical trials data. *Psychopharmacological Bulletin*, *27-1*, 73-77, 1991.

80. Daniel D.G., Goldberg T.E., **Gibbons R.D.** & Weinberger D.R. Lack of a bimodal distribution of ventricular size in schizophrenia: A Gaussian mixture analysis of 1056 cases and controls. *Biological Psychiatry*, *30*, 887-903, 1991.

81. **Gibbons R.D.**, Clark D.C & Fawcett J. Response to Bohning, Lindsay and Schlattman regarding statistical methodology for suicide cluster analysis. *American Journal of Epidemiology, 135*, 1312-1314, 1992.

82. Davis J.M., Janicak P.G, Wang Z.G., **Gibbons R.D.** & Sharma R.P. The efficacy of psychotropic drugs: Implications for power analysis. *Psychopharmacology Bulletin, 28*, 151-155, 1992.

83. **Gibbons R.D.**, Hedeker D.R., Elkin I., Waternaux C., Kraemer H.C., Greenhouse J.B., Shea M.T., Imber S.D., Sotsky S.M., & Watkins J.T. Some conceptual and statistical issues in analysis of longitudinal psychiatric data. *Archives of General Psychiatry*, *50*, 739-750, 1993.

84. **Gibbons R.D.**, and Hedeker D.R. Application of random-effects probit regression models. *Journal of Clinical and Consulting Psychology*, *62*, 285-296, 1994.

85. Hedeker D.R., **Gibbons R.D.**, & Flay B.R. Random regression models for clustered data: with an example from smoking prevention research. *Journal of Clinical and Consulting Psychology*, *62*, 757-765, 1994.

86. Elkin I., **Gibbons R.D.**, Shea M.T., Sotsky S.M., Watkins J.T., Pilkonis P.A. & Hedeker D. Initial severity and differential outcome in the NIMH treatment of depression collaborative research program. *Journal of Clinical and Consulting Psychology*, *63*, 841-847, 1995.

87. **Gibbons R.D.** Mixed-effects models for mental health services research. *Health Services and Outcomes Research Methodology*, *1*, 91-129, 2000.

88. **Gibbons R.D.**, Hur, K., Bhaumik, D.K., Mann, J.J. The relationship between antidepressant medication use and rate of suicide. *Archives of General Psychiatry*, *62*, 165-172, 2005.

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Other:

1. Robinson (PCCP) – Frye hearing testimony – 02/12/15-02/19/15

2. Robinson (PCCP) – Slides used during direct examination of Dr. Nicholas Jewell

3. Robinson (PCCP) – Expert report of Dr. Nicholas Jewell

4. Zoloft MDL – Expert report of Dr. Nicholas Jewell